REMARKS

Applicant and applicant's attorney thank the Examiner for once more providing a thorough examination and further searching that identified the Catt reference (U.S. 6,403,380). The examination resulted in a series of objections and one rejection under Section 112, all of which are overcome by way of the above amendment to the claims.

All of the claims were rejected on new grounds under Section 103, based in whole or part on Catt in view of Boehringer (WO 98/39657). Claim 18 was rejected on this basis but in further view of Cole, and claims 26 and 27 were rejected based on Catt in view of Boehringer in further view of O'Connor (U.S. 2003/0124737). Applicant requests reconsideration and allowance of the claims in view of the above amendments to the independent claims and the distinctions now noted.

It is respectfully submitted that, for multiple reasons, the independent claims 1, 10, 20 and 25 as now presented are non-obvious over Catt in view of Boehringer. The Examiner has already agreed that the Catt reference does not disclose test devices having a plurality of regions each responsive at a different sensitivity level to indicate presence of analyte based on capillary flow. Although the Boehringer reference has been cited for disclosing that which Catt does not disclose, the Examiner has not provided a prima facie case of obviousness. Rather, the rejection is a reconstruction. There is no apparent basis, other than hindsight in view of the applicant's teachings, for replacing the assay format disclosed in the Catt reference with the device of Boehringer. There is no objective evidence indicating obviousness.

Also, as previously noted, the Boehringer reference **only** addresses quantitation of analyte concentration relative to a **single** device such as shown in the figures, e.g., FIG 2. This limited disclosure supports applicant's contention of non-obviousness. The rejection extrapolates from the prior art to conclude that there is obviousness based on a combination only suggested by the applicant. The rejection apparently assumes, without providing any support, that there would be reason or motivation to replace the assay format used by Catt (see col. 9, lines 21-32) with the device of Boehringer. Yet none of the prior art recognizes the potential use of capillary flow from a receiving zone to provide an indication of a change in health.

In fact, the Catt reference, which relates to monitoring of fertility, is not concerned about whether change occurs, as it is well known that changes in fertility inevitably do occur during the ovulation cycle. Rather, the Catt reference concerns determining when an expected change does

occur in order to determine, for example, the onset of a fertile phase. The distinction between **whether** and **when** distinguishes monitoring according to the invention (e.g., to identify unpredictable outcomes, such as a change in health, which might occur at any time), from efforts to determine what day during a cycle an expected change actually occurs. Recognizing this difference between the Catt reference and the claimed invention, it is important to note further distinction rendering the prior art deficient: neither Catt nor Boehringer relate to monitoring changes in health, and since the Boehringer reference discloses nothing about monitoring any changes, there is no basis to combine and reconstruct the prior art to provide that which is claimed.

In this regard, the Examiner had cited O'Connor in relation to a level of hCG having been found to indicate the cause of early pregnancy loss [See page 14 of the Office Action] but this does not render the claims obvious. Rather, it merely confirms that applicant has claimed a useful combination for monitoring change. In fact the O'Connor reference discloses nothing useful over and above applicant's disclosure and discussion of prior art in the patent application. However, it is noted that the O'Connor reference, filed years after the Catt and Boehringer references, does not at all suggest the claimed invention for monitoring health. Rather, as indicated at par [0045] therein, it appears that O'Connor teaches use of laboratory procedures rather than, for example, the claimed test devices which are based on capillary flow. Thus neither Catt nor O'Connor are consistent with that which is claimed and it was necessary for the examiner to reconstruct the prior art (rather than to consistently combine the prior art) in order to re-create the claimed invention.

Based on the above deficiencies, the claims are distinguished because it is only the applicant who suggests, per claim 1, monitoring whether change occurs:

based on capillary flow of each sample from a sample receiving region on one of the first or second test devices to one or more of the plurality of regions on the same test device and the response on each device is based on an amount of binding of an antigen and an antibody to form complexes.

or, per claim 10:

determining whether a change in the health condition occurs, wherein a difference between visually observable responses ... each based on binding of an antigen and an antibody, **provides information about a change in the health condition** ...

Claims 20 and 25 are distinguished for similar reasons. Furthermore, claim 25 requires that

the visually observable response induced in the second test device **provides information about change in the health condition** without requiring determination of analyte concentration in the source on either occasion.

There does not appear to be any disagreement that the Boehringer reference fails to disclose, imply or suggest any methodology relating to change in health, e.g., based on obtaining samples from the same source on different occasions. The idea of determining change in health is not at all contemplated by the Boehringer reference. Nor does the Catt reference provide any disclosure relating to determining change in health.

Summary and Conclusion

In view of the above amendments and the distinctions described herein the claims each recite non-obvious subject matter. It would not be appropriate to combine any of the prior art to reject the claims because there is no consistent combination that would result in the claimed combinations. While it may be permissible to reconstruct the prior art, any such efforts cannot be inconsistent with the teachings and disclosure in the prior art. For example, O'Connor only teaches a laboratory procedure and there is no basis for extracting in piecemeal part of the "useful" disclosure of O'Connor while ignoring the inconsistency that O'Connor does not disclose any motivation or other basis for monitoring changes in health based on capillary flow of hCG. It is only in hindsight recognition of the applicant's teachings that the combination was made and, in fact, it was still necessary to pick and choose disclosure from among multiple references to form the rejection of claims 26 and 27.

For all of the above reasons allowance of the application is requested.

Respectfully submitted,

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